

Application No. 10/007,733
Reply dated 6 December 2004
Responsive to Final Office Action mailed on 19 October 2004

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AMENDMENT TO THE DESCRIPTION

Please replace the paragraph beginning on page 3 at line 8 of the application as originally filed with the following rewritten paragraph.

The achievement of urinary continence while awake may require both conditioning and the development of conscious awareness in the child of the physical sensation of a full or mostly full bladder. The method of this invention involves the identification of appropriate continence training opportunities, on which the caregiver can capitalize to help the child develop this conscious awareness. The term "appropriate", as used herein in relation to a continence training opportunity, refers to an occurrence or a condition that is especially suitable for use in training the child to achieve urinary continence, such as when the bladder contains a quantity of urine sufficient to warrant urination. Thus, the urinary continence training method of the present invention includes the steps of obtaining an objective measurement that is indicative of the physical state of the bladder and providing a signal to the child and/or to the caregiver when the value of the measurement reaches some signal threshold value corresponding to a full or relatively full bladder. These steps are shown in the flow charts of Figure 3, Figure 4, Figure 5, Figure 6, Figure 7, Figure 8, Figure 9, and Figure 10.

Please replace the paragraph beginning on page 3 at line 19 of the application as originally filed with the following rewritten paragraph.

The occurrence of this state of fullness of the bladder provides an appropriate opportunity to train the child to associate the physical sensation of a full or mostly full bladder with voluntary urination. By providing the signal based upon the objective measurement, this method can identify appropriate continence training opportunities to the caregiver, as shown in the flow charts of Figure 8 and Figure 10. Given this objective indication of relative bladder fullness, the caregiver may query the child about his or her perceived physical sensations as shown in the flow charts of Figure 4, Figure 5, and Figure 6, inform the child that urination is possible or imminent as shown in the flow charts of Figure 5 and Figure 6, take the child to the desired location for urination, place the child in the proper position to urinate into the designated receptacle as shown in the flow charts of Figure 6 and Figure 9, encourage the child to attempt urination, or perform any number of other acts that help the child associate the physical sensation of the full bladder with voluntary urination. Since this method is based on an objective measurement and does not require the child to communicate bladder fullness or the caregiver to

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guess when a continence training opportunity exists, this method of continence training is applicable to incontinent children of any age in the ranges noted above, at which continence training is begun in various cultures.

Please replace the paragraph beginning on page 3 at line 31 of the application as originally filed with the following rewritten paragraph.

Preferably, the signal threshold value is set such that it indicates a relatively full bladder containing less urine than in the state of fullness at which reflexive urination or other involuntary discharge of urine will occur. The term "reflexive" is used herein to refer to an action of the nervous system, below the level of consciousness, in which a muscular response to a stimulus is automatically effectuated. An example of an involuntary, but non-reflexive discharge of urine is that which may occur through leakage past the urinary sphincter due to excessive pressure. The volume of urine in the bladder at which the reflexive release of urine occurs is referred to herein as the "reflexive urination volume" of the bladder. The value of the objective measurement corresponding to the reflexive urination volume is referred to herein as the "reflexive urination level". This reflexive urination volume may be measured and used to determine the signal threshold value as shown in the flow charts of Figure 3, Figure 4, Figure 5, Figure 6, Figure 7, Figure 8, Figure 9, and Figure 10. Since the reflexive urination volume varies somewhat between different urination events, an average of the reflexive urination volume or of the corresponding reflexive urination level may be used to determine the signal threshold value. Alternatively, the lowest or highest observed reflexive urination volume, another empirically derived value, or even an arbitrary value, may be used to determine the signal threshold value. For example, the signal threshold value may be set to correspond to an average of the daytime urination volume.

Please replace the paragraph beginning on page 6 at line 32 of the application as originally filed with the following rewritten paragraph.

Preferably, the measurements indicative of the state of fullness of the bladder are performed by a bladder volume monitor or "bladder monitor" as shown in the flow charts of Figure 7 and Figure 10. A bladder monitor utilizing ultrasound may generally comprise one or more ultrasonic transducers adapted to send pulsed ultrasonic energy into the child's abdomen and to receive reflections of this energy. The bladder monitor also preferably includes the necessary

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software to generate a measurement of the bladder state on the basis of the reflected ultrasonic energy and to compare it to a threshold value. The bladder monitor also preferably includes one or more mechanisms to provide a signal or an alarm to the child and/or to the caregiver when the bladder signal reaches the threshold value. The signal or alarm may be provided in any useful form, such as an audible alarm, a tactile alarm, a visible alarm, and the like.

Please replace the paragraph beginning on page 7 at line 16 of the application as originally filed with the following rewritten paragraph.

The bladder monitor used in the method of the present invention may be a handheld unit or may comprise a wearable device. As used herein, the term "wearable" refers to the adaptability of the monitor, or a portion thereof, to be applied to a child's body for the duration of his or her normal activities without substantially limiting these activities as shown in the flow charts of Figure 7 and Figure 10. The scope of this term includes the association with, or incorporation into, a garment, the partial or full encirclement of at least a portion of the subject's anatomy, the adhesive application to the child's skin, or the design of the device to simulate a garment, belt, or any other known wearable garment. Wearable devices or components may include elastic and other belts, disposable or durable clothing, disposable absorbent articles such as diapers, disposable waste-receiving articles such as adhesively or releasably attachable strips such as bandages and diagnostic strips, adhesively attached devices, and other wearable items known in the art. Additionally, the device, or a component thereof, may be releasably affixed to any of the above wearable articles or to any other carrier structure that may be attached to the subject or to a wearable article.

Please replace the paragraph beginning on page 9 at line 3 of the application as originally filed with the following rewritten paragraph.

A packaged article of commerce may be useful in relation to the method of the present invention. Such an article of commerce may comprise, for example, a package including a bladder monitor and instructions for using the bladder monitor to perform the method of continence training described herein. Such a package 10 containing a bladder monitor 20 and instructions 30 is shown in Figure 11. The term "instructions" refers herein to an outline or manual of technical procedure. In general, the instructions may describe the use of the bladder monitor for any of the steps for which it can be used, as well as describing associated steps of the

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method. For example, the instructions may describe any of the steps mentioned, including those of using the bladder monitor to obtain the objective measurement, providing a signal when the measurement equals or exceeds a signal threshold value, and identifying an appropriate continence training opportunity based on the occurrence of the signal. The instructions may, likewise, describe other steps, including those of using the bladder monitor to measure the reflexive urination volume and setting the signal threshold value to correspond to a bladder volume that is less than the reflexive urination volume, for example.